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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,420	04/16/2004	Kyungyoon Min	F-6097 (9360-0145.01)	9851

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
03/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,420	MIN ET AL.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,10-14 and 20-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,10-14,20-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 February 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3-6, 10-12, 14, and 20-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,632,191 to Headley et al.

In the specification and figures, Headley discloses the method substantially as claimed by Applicant. With regard to claims 1, 3, 20, 21, 22, 27, 28, Headley discloses a method for collecting and separating whole blood comprising the steps of providing a disposable blood separation set (see FIG 1) that mounts on a reusable separator and control unit 20 (see column 3, lines 15-25). The disposable set comprises a cannula 10 or fluid flow path for communicating with a source, and a processing chamber 21.

Headley further discloses the steps of flowing fluid from a donor via cannula 10 directly into a processing chamber/rotor 21, processing the collected blood in the rotor to separate it into desired components, and disconnecting the donor from the system after processing begins, but before the plasma is urged from the rotor, so before the processing ends (see column 4, lines 1-10).

Headley fails to disclose that the blood from the donor is collected in two separate chambers. However, Headley discloses that prior art methods utilized an initial collection container 12 with anticoagulant. The prior art method comprised the steps of

flowing blood from the donor into the initial container, disconnecting the patient from the set before blood is processed, and processing the collected blood to separate into the desired components (see column 1, lines 25-60). Taken together, the embodiment disclosed by Headley and the prior art system suggests that a blood separation circuit may comprise both an initial collection bag and a separation chamber that are capable of holding collected blood before processing. One of ordinary skill in the art may use both chambers to hold blood in the event that the donor is qualified to donate more blood than either the initial storage container or processing chamber alone can hold. Rather than perform two needle sticks or make the patient wait for processing to be complete before disconnection, the use of two collection containers minimizes trauma and downtime for the patient. As such, one having ordinary skill in the art would have, at the time of invention, been motivated to add the steps of flowing blood into an initial collection chamber and a processing chamber, processing what's been collected in the processing chamber while the second chamber fills, and disconnecting the patient as soon as a sufficient quantity of blood has been collected, allowing the patient to leave the donation center before all processing is complete.

With regard to claims 4-6, 14, Headley discloses that the rotor or collection chamber in the disclosed embodiment has a variable volume (see column 3, lines 15-34). It has been held that where the general conditions of a claim are disclosed in the prior art, it is within the skill of a worker in the art to discover the optimum or workable ranges by routine experimentation. See MPEP 2144.05(II)(A). Since Headley specifically discloses that the volume of blood collected may vary from patient to patient,

it is the position of the examiner that the amount of whole blood collected is a result-effective variable, the optimization of which is within the skill of a worker in the art.

With regard to claim 10, Headley discloses that the blood source is a "donor," (see column 1, lines 25-30), which is well-known in the art to comprise a human donor (see US 5,906,589 to Gordon et al that discloses apheresis blood supply as typically a human donor/patient at column 3, lines 55-60).

With regard to claims 11 and 12, Headley discloses that the system and method may be use to separate all the collected blood into constituent components simultaneously (see column 4, lines 20-30) or sequentially, wherein plasma is removed from the blood before RBC separation (see column 4, lines 13-16).

With regard to claim 21, Headley discloses that, in one embodiment, blood is flowed from the donor directly into rotor 21, corresponding to Applicant's blood processing chamber.

With regard to claim 23, Headley discloses that the fluid circuit comprises clamps 27, 25, 26 to control fluid flow between the various chambers of the apparatus. Headley does not disclose that such valves or clamps are located between the donor and the collection containers. However, since clamps or valves are known in the art to control fluid flow (as disclosed by Headley above), it would have been obvious to one having ordinary skill in the art to add a clamp or valve in a location where flow control is desired (such as in a location that directs fluid flow from one container to another) in order to direct the collected fluid to the desired location.

With regard to claims 24, 25, 29, and 30, Headley fails to disclose or suggest the order in which blood is flowed into the collection containers—sequentially or simultaneously. However, it has been held that the selection of any order of performing process steps is obvious in the absence of new or unexpected results. See MPEP § 2144.04 (IV)(C). In the instant case, Applicant has not provided any evidence that the order in which the blood is collected in each container provides any new or unexpected results. Accordingly, it is the position of the Examiner that the order in which blood is collected in the collection containers is an obvious variation of the collection and processing method suggested by Headley.

With regard to claims 26 and 31, it follows naturally that if blood is collected into two chambers, one of which is a processing chamber, the blood collected in the initial collection chamber will necessarily flow from that container to the blood processing chamber.

3. Claims 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,632,191 to Headley et al in view of US 6,743,192 to Sakota et al.

In the specification and figures, Headley suggests the method substantially as claimed by Applicant (see rejection above) with the exception of providing additional whole blood bags and pooling whole blood before processing. Sakota discloses a blood apheresis apparatus and method comprising a disposable fluid circuit with a phlebotomy needle 24 that connects to a donor. The phlebotomy needle may be replaced with a whole blood bag in case whole blood is to be pooled and then supplied to the apheresis system (see column 6, lines 55-65) in order to increase the amount of whole blood

processed in a single round of apheresis (see column 2, line 56 to column 3, line 37). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add the additional containers and pooling whole blood as disclosed by Sakota in the process suggested by Headley in order to increase the volume of whole blood processed, as taught by Sakota.

Response to Arguments

4. Applicant's amendment and arguments filed 12 December 2008 have been entered and considered.

5. Applicant's arguments have been fully considered, and are persuasive with regard to the prior rejection as applied to the claims as amended. However, in light of the amendments, a new rejection is presented above.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
5 March 2009